



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

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Food and Drug Administration  
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November 26, 2002

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mark E. Goldstein, CEO  
Neoteric Cosmetics, Inc.  
Division of Scott's Liquid Gold, Inc.  
4889 Havana Street  
Denver, CO 80239

Ref: DEN#-03-06

Dear Mr. Goldstein:

This letter is in reference to your firm's marketing and distribution of the products "Neoteric Diabetic Skin Care Oxygenated Therapeutic Moisturizer Lotion" and "Neoteric Diabetic Skin Care Oxygenated Advanced Healing Cream." Statements made on your website, [www.touchofscents.com](http://www.touchofscents.com), labels, and labeling collected during our inspection of your firm from November 28 through December 3, 2001, demonstrate that these products are being marketed to diabetics.

The claims on the carton label of your product "Neoteric Diabetic Skin Care Oxygenated Therapeutic Moisturizer Lotion" include "Diabetic skin care ... for the special skincare needs of the diabetic ... dual-action treatment to renew and prevent ... damaged skin ..."

The container label for "Neoteric Diabetic Skin Care Oxygenated Advanced Healing Cream" claims it "Provides intensive treatment for ... damaged skin. Patented TriOxygen, clinically proven to increase circulation ..." The carton label for this product

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claims that "Neoteric Diabetic Skin Care provides exceptional care for diabetics ... Patented TriOxygen is clinically proven to increase circulation and speed healing ..."  
Promotional literature that accompanies each shipment of "Neoteric Diabetic Skin Care Oxygenated Advanced Healing Cream" contains not only the product name which targets the diabetic population, but also disease claims that include "Diabetes can deprive the skin of sufficient oxygen...Neoteric Diabetic Skin Care contains TriOxygen, a patented ingredient that infuses oxygen into the skin." "70% of diabetic study subjects reported improvement in skin problems affecting Diabetics;" "Clinically shown to help reduce healing time in 77% of patients studied"; and "Releases oxygen into the skin, helping increase circulation and strengthening its natural defenses."

Various pieces of promotional material for "Neoteric Diabetic Skin Care Oxygenated Advanced Healing Cream" also include photos of what appear to be, or are implied to be, ulcerated skin before use of your product and healed skin after use of your product with the caption that includes the claim "Advanced Healing Cream, when tested against a placebo, provided an environment that protected the skin and allowed it to heal faster." Therefore, the combination of product name, claims, and photographs indicate that your product is promoted and marketed to treat serious skin conditions prevalent in the diabetic population. In addition, some promotional material also includes reference to your product "Neoteric Diabetic Skin Care Oxygenated Therapeutic Moisturizer Lotion." Displaying both of your products on the same page with the Healing Cream claims implies that the claims cited above are being made for both products.

The "www.touchofscents.com/ neotericdiabetic2" website, on which you offer the products for sale, also includes a webpage, titled "The benefits are clinically proven..." It contains the product name targeting a patient population; disease claims that include "... decreased healing time in 77% of diabetic patients; Releases oxygen to the skin, increasing circulation and strengthening the skin's natural defenses; 70% of diabetic subjects reported improvement in common skin problems affecting diabetics ", and photographs of what appears to be a diabetic skin ulcer with the caption "... protected the skin and allowed it to heal faster."

Based on the claims made for these products to affect the structure or function of the body, and to treat, prevent, and mitigate disease, they are "drugs" within the meaning of section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). Moreover, these

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products are "new drugs" [section 201(p) of the Act] because there is not substantial evidence that these products are generally recognized as safe and effective for their intended uses. Since these products are "new drugs" they may not be marketed in the United States without approved new drug applications [section 505(a) of the Act].

Furthermore, these drugs are misbranded [section 502(f)(1) of the Act] because the labeling fails to bear adequate directions for use for the conditions for which they are offered.


This letter is not intended to be an all inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to the attention of Ms. Shelly L. Maifarth, Compliance Officer, at the letterhead address.

Sincerely,



B. Belinda Collins  
Director, Denver District

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